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## **DETAILED ACTION**

### ***Status of Claims***

1. This office action is in response to the claim amendments and remarks filed on 03/09/2011.
2. None of claims have been amended. Claim 17 has been previously cancelled.
3. Claims 1-16 and 18 are now pending in this application.

### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-16 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

A claimed process is eligible for patent protection under 35 U.S.C. § 101 if: "(1) It is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. See Benson, 409 U.S. at 70 ('Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines.');

Diehr, 450 U.S. at 192 (holding that use of mathematical formula in process 'transforming or reducing an article to a different state or thing' constitutes patent-eligible subject matter); see also Flook, 437 U.S. at 589 n.9 ('An argument can be made [that the Supreme] Court has only recognized a process as within the statutory definition when it either was tied to a particular apparatus or

operated to change materials to a 'different state or thing' '); *Cochrane v. Deener*, 94 U.S. 780, 788 (1876) ('A process is...an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.').<sup>7</sup> A claimed process involving a fundamental principle that uses a particular machine or apparatus would not pre-empt uses of the principle that do not also use the specified machine or apparatus in the manner claimed. And a claimed process that transforms a particular article to a specified different state or thing by applying a fundamental principle would not pre-empt the use of the principle to transform any other article, to transform the same article but in a manner not covered by the claim, or to do anything other than transform the specified article." (*In re Bilski*, 88 USPQ2d 1385, 1391 (Fed. Cir. 2008)).

Also noted in *Bilski* is the statement, "Process claim that recites fundamental principle, and that otherwise fails 'machine-or-transformation' test for whether such claim is drawn to patentable subject matter under 35 U.S.C. §101, is not rendered patent eligible by mere field-of-use limitations; another corollary to machine-or-transformation test is that recitation of specific machine or particular transformation of specific article does not transform unpatentable principle into patentable process if recited machine or transformation constitutes mere 'insignificant post-solution activity.'" (*In re Bilski*, 88 USPQ2d 1385, 1385 (Fed. Cir. 2008)) Examples of insignificant post-solution activity include data gathering and outputting. Furthermore, the machine or transformation must impose meaningful limits on the scope of the method claims in order to pass the machine-or-transformation test. It is also noted that the mere recitation of a machine in the preamble in a manner such that the machine fails to

patentably limit the scope of the claim does not make the claim statutory under 35 U.S.C. § 101, as seen in the Board of Patent Appeals Informative Opinion Ex parte Langemyr et al, (Appeal 2008-1495).

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 4, 5, 7-9, 13, 15, 16, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al. (**US 2002/0154010 A1**).

#### **With respect to claim 1:**

Tu et al. teaches *a method for a clinical study, in which an occurrence of an event during the study elicits collaboration between responsible study personnel, the collaboration being an exchange of at least one of opinions, agreements, knowledge and findings, the exchange being at least one of written, verbal and electronic, the method comprising:*

Tu et al. teaches the method comprising:

- *receiving the event at a collaboration system; the collaboration system being at least one of an electronic data processing system and a communications system; (By disclosing, Upon **detection of various events and/or***

**conditions with respect to the events**, the present invention enables a notification message to be sent in accordance with a set of notification preferences. See at least paragraph [0018] and fig. 1 as well as associated text)

- *identifying, via the collaboration system and on the basis of parameters assigned to the event, a group of responsible study personnel needed for the collaboration;* (By disclosing, notification may be provided to the **appropriate entities** in a manner suitable for the situation prompting the notification. See at least paragraph [0018].)
- *providing, via the collaboration system, a communications platform for the group to undertake the collaboration;* (By disclosing message bus in fig. 1. See at least fig. 1 as well as associated text.)
- *checking, via the collaboration system, the collaboration on the basis of verification criteria.* (By disclosing, one or more metrics may be flagged to identify one or more values that are to be monitored in association with the event. Thus, each condition may be satisfied with respect to one or more attributes and/or one or more metrics. See at least paragraph [0020].)

**With respect to claim 2:**

Tu et al. teaches limitations shown above. Tu et al. further teaches *the collaboration system, as a communications platform, provides a central information bus and provides each responsible study personnel member of the group with an*

*information channel to the information bus.* (By disclosing message bus in fig. 1. See at least fig. 1 as well as associated text.)

**With respect to claims 4 and 13:**

Tu et al. teaches limitations shown above. Tu et al. further teaches *the collaboration system, using the parameters assigned to the event, establishes a content or time framework for the collaboration and communicates this to the group.* (See at least paragraph [0022].)

**With respect to claim 5:**

Tu et al. teaches limitations shown above. Tu et al. further teaches *the collaboration system uses at least one of content and time framework as a verification criterion and, when the collaboration is over, checks compliance with the verification criteria.* (By disclosing, In addition, timing flows (e.g., fired timer events) are further indicated by dotted lines. Thus, in this example, if the second following event is never received, or not received within the specified time, the stored event data for the entering event (i.e., first event) is located at block 2642 and discarded at block 2644. More particularly, the persist flag may be checked to verify that the event is to be discarded in association with the follow-by paired event condition. See at least paragraph [0124].)

**With respect to claims 7 and 15:**

Tu et al. teaches limitations shown above. Tu et al. further teaches *the event is a prompt for collaboration which is defined within the framework of the study.* (See at least paragraph [0113].)

**With respect to claims 8 and 16:**

Tu et al. teaches limitations shown above. Tu et al. further teaches *the event is an unforeseeable event arising during the study*. (See at least paragraph [0066].)

**With respect to claim 9:**

Tu et al. teaches limitations shown above. Tu et al. further teaches *the event is found by a monitoring system combing through the study database data for anything striking*. (See at least paragraph [0022].)

**With respect to claim 18:**

Tu et al. teaches limitations shown above. Tu et al. further teaches

- the collaboration system includes a collaboration module configured to perform the receiving step; (By disclosing, the adapter 101. see at least paragraph [0060])
- the collaboration system includes a communication module configured to perform the providing step; and (By disclosing, message bus 110 and notification media. see at least paragraph [0060])
- the collaboration system includes a monitoring module configured to perform the checking step. (By disclosing, the adapter 101. see at least paragraph [0060])

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:



(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 3, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. (**US 2002/0154010 A1**) in view of Wagner (**US 6,092102 A**).

**With respect to claims 3 and 12:**

Tu et al. teaches limitations shown above. Tu et al. does not specifically disclose *the collaboration system, ascertains, using the parameters assigned to the event, available data needed for collaboration that are in at least one of a database containing medical knowledge and study database, extracts the data from the database, and makes the data available to the group on the communications platform.* However Wagner teaches *the collaboration system, ascertains, using the parameters assigned to the event, available data needed for collaboration that are in at least one of a database containing medical knowledge and study database, extracts the data from the database, and makes the data available to the group on the communications platform.* (see at least fig. 1 as well as associated text.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of collaboration disclosed by Tu et al. with the technique of extracts the data from the database, and makes the data available to the group on the communications platform disclosed by Wagner to improve the quality and lower the cost of health care by providing information to health care providers as they need it. Furthermore, merely combining well known elements in the prior art with predictable results does not render an invention patentably distinct over such combination.

**With respect to claim 14:**

Tu et al. teaches limitations shown above in view of Wagner. Tu et al. further teaches *the collaboration system, using the parameters assigned to the event,*

*establishes a content or time framework for the collaboration and communicates this to the group.* (See at least paragraph [0022].)

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al.

**(US 2002/0154010 A1)** in view of Schmidt et al. **(US 6,839,678 B1)**.

**With respect to claim 6:**

Tu et al. teaches limitations shown above. Tu et al. does not specifically disclose *a person who was not involved in the study prior to the occurrence of the event is included in the study and in the group, as a responsible personnel member*. However Schmidt et al. teaches *a person who was not involved in the study prior to the occurrence of the event is included in the study and in the group, as a responsible personnel member*. (See at least column 5, 1<sup>st</sup> paragraph.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method of collaboration disclosed by Tu et al. with the technique of having *a person who was not involved in the study prior to the occurrence of the event is included in the study and in the group, as a responsible personnel member* disclosed by Schmidt et al. so no eligible person left out of study. Furthermore, merely combining well known elements in the prior art with predictable results does not render an invention patentably distinct over such combination.

12. Claims 10 and 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Tu et al. **(US 2002/0154010 A1)** in view of Horstmann **(US 2005/0055241**

**A1)**.

**With respect to claims 10 and 11:**

Tu et al. teaches limitations shown above. Tu et al. may or may not specifically disclose *the collaboration is documented and the collaboration is archived*. However Horstmann teaches *the collaboration is documented* (By disclosing, the document collaboration means and the tracking means facilitate the generation of documents and the document collaboration means provides real-time capability so that collaborations may be done by one or more individuals, who preferably review the same document, at the same time, and are able to see the comments, suggestions or changes of the other collaborating individuals. See at least paragraph [0066]) *and the collaboration is archived*. (By disclosing, the document collaboration means provides a version controlled status, and enables archiving each iteration. See at least paragraph [0066]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method disclosed by Tu et al. with the technique of documenting and archiving as disclosed by Horstmann so study personnel's opinion and result of study can be useful for future studies which make less work in upcoming studies. Furthermore, merely combining well known elements in the prior art with predictable results does not render an invention patentably distinct over such combination.

### ***Response to Arguments***

As to the remark, Applicant asserted that

- a. Claims 1-16 and 18 overcome 35 U.S.C. 101 rejections as claim 1 is tied to a particular machine or apparatus namely "the collaboration system".
- b. Tu does not teach or fairly suggest "providing, via the collaboration system, a communications platform for the group to undertake the collaboration," where "the collaboration being an exchange of at least one of opinions, agreements, knowledge and findings, the exchange being at least one of written, verbal and electronic," as required by claim 1.
- c. Tu does not teach *checking, via the collaboration system, the collaboration on the basis of verification criteria*

Examiner respectfully traverses Applicant's remark for the following reasons:

With respect to (a) Examiner would like to point out to the applicant that under *the Interim Bilski Guidance*, the machine-or-transformation test remains an investigative tool and is a useful starting point for determining whether a claimed invention is a patent-eligible process under 35 U.S.C. 5 101. The machine or transformation must impose meaningful limits on the scope of the method claims in order to pass the machine-or-transformation test, While it appear to the examiner that broadest reasonable interpretation of claim limitation "*the collaboration system being **at least one of** an electronic data processing system and a communications system;*" cover communication system which can be exchanging words or manually writing messages. Hence, the recited steps of the method are held to be non-statutory subject matter because the recited steps of the method are (1) not tied to a particular machine or

apparatus or (2) not transforming the underlying subject matter (such as an article or materials ) to a different state or thing. "the collaboration system" as define in specification (The collaboration system can for example be an electronic data processing or administration system or a service provider in charge of the performance of the clinical study or **an individual person or a group of persons**. See paragraph [0014]) can be group of persons which make claim non-statutory.

With respect to (b) Examiner would like to point out to the applicant that *"providing, via the collaboration system, a communications platform for the group to undertake the collaboration,* (By disclosing, **the exception server 122 enables collaboration between the entities that are assigned various exceptions**. See at least paragraph [0064] and **the message bus 110 connects other entities within or associated with the business such as users of a business enterprise system (e.g., business employees) to the event detection and notification system**, the adapter 102 may obtain data provided by these entities via the message bus 110. It is also contemplated that the data may be obtained or received from a source outside the business, such as via the Internet. See at least paragraph [0060]) *where "the collaboration being an exchange of at least one of opinions, agreements, knowledge and findings, the exchange being at least one of written, verbal and electronic,"* as required by claim 1. (Tu disclose collaboration being discussion between the entities to solve problem which inherently an exchange of at least one of opinions, agreements, knowledge and findings, the exchange being at least one of written, verbal and electronic.). As the structural elements of "the collaboration system" is not defined in

claim, the collaboration system can be anything that facilitate discussion between entities. Tu facilitating collaboration between the entities system to solve problem followed by event notification.

With respect to (c) Examiner would like to point out to the applicant the Tu does teach *checking, via the collaboration system, the collaboration on the basis of verification criteria* (By disclosing, one or more metrics may be flagged to identify one or more values that are to be monitored in association with the event. Thus, each condition may be satisfied with respect to one or more attributes and/or one or more metrics. See at least paragraph [0020] and also by disclosing, In addition, the exception server 122 enables collaboration between the entities that are assigned various exceptions. For instance, this may be accomplished through various graphical user interfaces that enable communication between the entities. See at least paragraph [0064]). Examiner interpret this various exceptions as verification criteria.

### ***Conclusion***

13. All previously outstanding objections and rejections to the Applicant's disclosure and/or claims not contained in this Office Action have been respectfully withdrawn by the Examiner hereto.
14. Applicant's arguments with respect to claims filed on 03/09/2011 have been considered but they are not persuasive. Accordingly, **THIS ACTION IS MADE FINAL.**

15. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Neha Patel** whose telephone number is **571.270.1492**. The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JERRY, O'CONNOR** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see



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April 29, 2011

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